"Express Mail" Label No. <u>EL 815807577 US</u> Date of Deposit <u>February 14, 2002</u>

Assistant Commissioner for Patents Washington, D.C. 20231

Attorney Docket No.: 016930-000630US
Client Reference No.: 3001-1

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michael H. Shepard et al.

Application No.: Unassigned

Filed: Herewith

For: METHOD FOR SELECTIVELY TRANSDUCING PATHOLOGIC MAMMALIAN CELLS USING A TUMOR SUPPRESSOR GENE Examiner:

Unassigned

Art Unit:

Unassigned

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and

**§1.98** 

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are not enclosed, since they were cited in the parent case, U.S. Application No. 08/403,797. Enclosed is a copy of the Search/Examination report corresponding to the PCT application. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Michael H. Shepard et al. Application No.: Page 2

Applicant believes that <u>no fee is required</u> for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Joseph R. Snyder Reg. No. 39,381

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8<sup>th</sup> Floor San Francisco, California 94111-3834

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

	Complete if Known	
Application Number	08/403,797	2
Filing Date	December 4, 1995	Δ.
First Named Inventor	Shepard, H. Michael	L S
Group Art Unit	1633	
Examiner Name	Dave Nguyen	27.5
Attorney Docket Number	016930-000600US	<u>`</u> 5

				U.S. PATENT DOCUM	MENTS	
Examiner Initials *	Cite No.1	U.S. Patent Docum  Kind Co	ode <sup>2</sup>	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
	1	5,087,617	vii)	Smith	MM-DD-YYYY 02/11/1992	Figures Appear
	2	5,252,479		Srivastava	10/12/1993	
	3	5,834,256		Finer et al.	11/10/1998	
	4	5,219,740		Miler et al.	06/15/1993	
	5	5,532,220	<del></del>	Lee et al.	07/02/1996	
	6	5,248,671		Smith	09/28/1993	
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	Ī	For	eign Patent Do	cument	Name of Patentee	Date of Publication of	Pages, Columns, Lines, Where Relevant	
Examiner Initials*	Cite No. <sup>1</sup>	Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	T <sup>6</sup>
	7.	PCT	WO 91/1558	0		10/17/1997		
	8	PCT	WO 93/1081	4		06/10/1993		
	9	EP	0 475 623 A	J		08/23/1991		
	10	PCT	93/08844			09/17/1993		
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Examiner Signature	Date Considered	

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 5

	Complete if Known	
Application Number	08/403,797	
Filing Date	December 4, 1995	
First Named Inventor	Shepard, H. Michael	
Group Art Unit	1633	
Examiner Name	Dave Nguyen	
Attorney Docket Number	016930-000600US	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	<del>,                                     </del>
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	11	Anderson, "Human Gene Therapy," Science, 256:808-813 (1992)	
	12	Baker et al., "Suppression of Human Colorectal Carcinoma Cell Growth by Wild-Type p53," Science, 249:912-915 (1990)	
	13	Callahan, "p53 Mutations, Another Breast Cancer Prognostic Factor," J. Natl. Canc. Inst., 84(11):826-827 (1992)	
	14	Casey et al., "Growth suppression of human breast cancer cells by the introduction of a wild-type p53 gene," Oncogene, 6:1791-1797 (1991)	
	15	Chen et al., "Genetic Mechanisms of Tumor Suppression by the Human p53 Gene," Science, 250:1576-1580 (1990)	
	16	Chen et al., "Expression of wild-type p53 in human A673 cells suppresses tumorigenicity but not growth rate," Oncogene, 6:1799-1805 (1991)	
	17	Cheng et al., "Suppression of acute Lymphoblastivc Leukemia by the Human Wild-Type p53 Gene," Cancer Research, 52(1):222-226 (1992)	
	18	Correll et al., "Production of human glucocerebrosidase in mice after retroviral gene transfer into nutipotential hematopoietic progenitor cells," <i>Proc. Natl. Acad Sci. U.S.A.</i> , <b>86</b> :8912-8916 (1989)	
	19	Crystal, R.G., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," Science, 270:404-410 (1995)	
	20	Danos et al., "Safe and efficient generation of recombinant retroviruses with amphotropic and ecotropic host ranges," Proc. Natl. Acad. Sci. (U.S.A.), 65:6460-6464 (1988)	
	21	Droz et al., "Long-term Survivors after Salvage High Dose Chemotherapy with Bone Marrow Rescue in Refractory Germ Cell Cancer," Eur. J. Cancer, 27(7):831-835 (1991)	
	22	Finlay et al., "The p53 Prote-oncogene can act as a Supressor of Transformation," Cell, 57:1083-1093 (1989)	
	23	Friedmann, T., Cancer Supp, 70(6):1810-1817 (1991)	
	24	Gaidano et al., "p53 mutations in human lymphoid malignancies Association with Burkitt lymphona and chronic lymphocytic leukemia," <i>Proc. Natl. Acad. Sci. (U.S.A.)</i> , 88:5413-5417.(1991)	
	25	Gerwin et al., "Mutant p53 can induce tumorigenic conversion of human bronchial epithlial cells and reduce their responsiveness to a negative growth factor, transforming growth factor β₁" <i>Proc. Natl. Acad. Sci. (U.S.A.)</i> , 89:2759-2763 (1992)	

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•	Signature	Considered

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Sheet 3 of 5

	Complete if Known	
Application Number	08/403,797	
Filing Date	December 4, 1995	
First Named Inventor	Shepard, H. Michael	
Group Art Unit	1633	
Examiner Name	Dave Nguyen	
Attorney Docket Number	016930-000600US	
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		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	<del>,</del>
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
	26	Guild et al., "Retroviral transfer of a murine cDNA for multidrug resistance confers pleiotropic drug resistance to cells without prior drug selection," Proc. Natl. Acad. Sci. (USA), 85:1595-1599 (1988)	
···	27	Guttierrez et al., "Gene therapy for-Cancer," The Lancet, 339:715-721 (1992)	
	28	Isaacs et al., "Wild-Type p53 Suppresses Growth of Human Prostate Cancer Cells Containing Mutant p53 Alleles," Cancer Research, 51:4716-4720 (1991)	
	29	Isola et al., "Association of Overexpression of Tumor Suppressor Protein p53 with Rapid Cell Proliferation and Poor Prognosis in Node-Negative Breast Cancer Patients," J. Natl. Canc. Inst., 84(14):1109-1114 (1992)	
	30	Johnson et al., "Expression of Wild-Type p53 is not Compatible with Continued Growth of p53-Negative Tumor Cells," <i>Molecular and Cellular Biology</i> , 11(1):1-11 (1991)	
	31	Lavigueur et al., "High incidence of Lung, Bone, and Lymphoid Tumors in Transgenic Mice Overexpressing Mutant Alleles of the p53 Oncogene," <i>Molecular and Cell Biology</i> , <b>9</b> (9):3982-3991 (1989)	
	32	Ledley et al., "Clinical Considerations in the Design of Protocols for Somatic Gene Therapy," Human Gene Therapy, 2:77-83 (1991)	
	33	Lee, "Tumor suppressor genes: a new era for molucular genetic studies of cancer," Breast Cancer Research and Treatment, 19:3-13 (1991)	
	34	Levine et al., "The p53 tumour suppressor gene," Nature, 351:453-456 (1991)	
	35	Malkin et al., "Germ Line p53 Mutations in a Familial Syndrome of Breast Cancer, Sarcomas, and Other Neoplasms," Science, 250:1233-1238 (1990)	
	36	Miller et al., "Gene Transfer by Retrovirus Vectors Occurs Only in Cells That Are Actively Repoicating at the Time of Infection," <i>Molecular and Cellular Biology</i> , <b>10</b> (8) :4239-4242(1990)	
	37	Miller et al., "p53 Mutations in Human Lung Tumors," Cancer Research, 52:1695-1698 (1992)	
	38	Nigro et al., "Mutations in the p53 gene occur in diverse human tumour types," Nature, 342:705-708 (1989)	
-	39	Rill et al., "An Approach for the Analysis of Relapse and marrow Reconstitution After Autologous Marrow Transplantation Using Retrovius-Mediated Gene Transfer," <i>Blood</i> , <b>79</b> (10):2694-2700 (1992)	
	40	Rotter et al., "p53 and Human malignancies," Advances in Cancer Research, 57:257-272 (1991)	

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Signature	<u> </u>	Considered	1	

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#### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of

**Application Number** 08/403,797 December 4, 1995 **Filing Date First Named Inventor** Shepard, H. Michael Group Art Unit 1633 Dave Nguyen **Examiner Name** Attorney Docket Number 016930-000600US

	· 	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	_	
Examiner Initials *	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	41	Shaw et al., "Induction of apoptosis by wild-type p53 in a human colon tumor-derived cell line," <i>Proc. Natl. Acad. Sci.</i> (U.S.A.), 89:4495-4499 (1992)		
<u> </u>	42	Sikora, K., "Gene therapy for cancer," TIBTECH, 11:197-201 (1993)		
	43	Srivastava et al., "Germ-line transmission of a mutated p53 gene in a cancer-prone family with Li-Fraumeni syndrome," <i>Nature</i> , <b>348</b> :747-749 (1990)		
	44	Takahashi et al., "The retinoblastoma gene functions as a growth and tumor suppressor in human bladder carcinoma cells," <i>Proc Natl. Acad Sci. (U.S.A.)</i> , <b>88</b> :5257-5261 (1991)		
	45	Takahashi et al., "Wild-type but not Mutant p53 Suppresses the Growth of Human Lung Cancer Cells Bearing Multiple Genetic Lesions," Cancer Research, 52:2340-2343 (1992)		
	46	Thor et al., "Accumulation of p53 Tumor Suppressor Gene Protein: An Independent marker of Prognosis in Breast Cancers," J. Natl. Canc. Inst., 64(11):845-855 (1992)		
	47	Shaw et al., "Induction of apoptosis by wild-type p53 in a human colon tumor-derived cell line," <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 89(10):4495-4499 (1992)		
	48	Yerly-Motta et al., "Comparative preclinical study of three bone marrow purging methods using PCR evaluation of residual t(14;18) lymphona cells," Leuk. Lymphoma, 23 (3-4):313-321(1996)		
	49	Pei et al., "Preliminary application of a low molecular weight tumor suppressor in purged autologous bone marrow transplantation," <i>The Cancer Journal</i> , Vol. 5 (1992)		
	50	Cone et al., PNAS, 81:6349-6353 (1984)		
	51	Pei et al., EMBASE database, AN: 92206003, Cancer Journal, 5/3:142-145 (1992)		
	52	Chen et al., <i>Oncogene</i> , 8:1799-1805 (1991)		
	53	Friedmann, Cancer Supplement, 70,6:1810-1817 (1992)	_	
	54	Huang et al., Science, 242:1563-1566 (1988)		
	55	Masdasingelo et al., in Oncology, 23,1:4-21 (1996)	_	
Examiner Signature		Date Considered		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Complete if Known Substitute for form 1449B/PTO 08/403,797 **Application Number** INFORMATION DISCLOSURE Filing Date December 4, 1995 STATEMENT BY APPLICANT **First Named Inventor** Shepard, H. Michael 1633 Group Art Unit (use as many sheets as necessary) **Examiner Name** Dave Nguyen Attorney Docket Number 016930-000600US of | 5 Sheet

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	_
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	56	Culver et al., "Gene therapy for solid tumors," British Medical Bulletin, 51:192-204 (1995)	
	57	Carbone et al., "In vivo gene therapy of human lung cancer using wild-type p53 delivered by a retrovirus," J. Natl. Cancer Inst., 86:1437-1438 (1994)	
	58	Huang et al., "Suppression of the neoplastic phenotype by replacement of the RB gene in human cancer cells," Science, 242:1563-1566 (1988)	

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Signature	Considered

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